

510(k) SUMMARY

NOV 25 2002

SUBMITTER NAME: Ascension Orthopedics, Inc.
8200 Cameron Road, C-140
Austin, TX 78754-3832

510(k) CONTACT: Robert M. Wolfarth
Phone: (512) 836-5001

TRADE NAME: Ascension® Silicone MCP

COMMON NAME: finger joint implant

CLASSIFICATION: 21 CFR §888.3230, finger joint, polymer, constrained prosthesis
(Class II)

PRODUCT CODE: 87 KYJ

PANEL: Orthopedic Devices

PREDICATE DEVICE:

The DePuy Silicone MCP (K970544), which was determined by the FDA to be substantially equivalent to the Sutter Avanta MCP Joint Prosthesis and the Dow Corning Wright Swanson Finger Joint Implant on September 12, 1997.

DEVICE DESCRIPTION:

The Ascension® Silicone MCP is an anatomically designed, single-use, one-component hinged prosthesis designed to be implanted without bone cement across the metacarpophalangeal joint. It is made from flexible, injection-molded, medical grade silicone elastomer. The proximal and distal stems of the Ascension Silicone MCP are pre-flexed at 30° to match the approximate natural 30° flexion stance of the relaxed human hand.

INTENDED USE:

The Ascension® Silicone MCP is intended for cementless replacement of the metacarpophalangeal (MCP) joint of the finger where disabled by rheumatoid, degenerative, or traumatic arthritis.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Performance tests and analyses demonstrate that the Ascension® Silicone MCP is substantially equivalent to the predicate device.



NOV 25 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Robert M. Wolfarth
Senior Regulatory Affairs Specialist
Ascension Orthopedics, Inc.
8200 Cameron Road, Suite C-140
Austin, Texas 78754-3832

Re: K022892

Trade/Device Name: Ascension® Silicone MCP
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KYJ
Dated: August 29, 2002
Received: August 30, 2002

Dear Mr. Wolfarth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

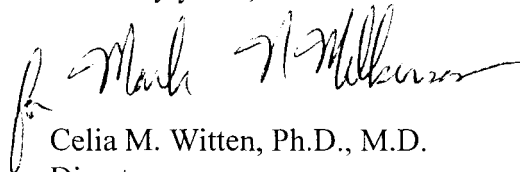
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Robert M. Wolfarth

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(K) Number: K022892

Device Name: Ascension® Silicone MCP

Indications for Use:

The Ascension® Silicone MCP is intended for cementless replacement of the metacarpophalangeal (MCP) joint of the finger where disabled by rheumatoid, degenerative, or traumatic arthritis.

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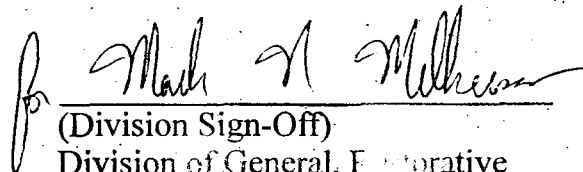
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General, F...orative
and Neurological Devices

510(k) Number _____

K022892